ROSWELL PARK MEMORIAL INSTITUTE

Department of Health ▪ State of New York

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November 12, 1981

Mr. Matthew L. Myers
Division of Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission
Washington, D.C. 20580

Dear Mr. Myers:

I have examined carefully the material that you brought to Buffalo indicated in your Table of Contents as Items 1 through 16, together with the more recent submission containing a letter and Attachment A from Mr. Witt; a letter from Dr. Gori addressed to Mr. London; a submission by Paul, Weiss, Rifkind, Wharton & Garrison; together with a technical appendix and technical report prepared by Dr. Kamm. The total body of material does not convince me that the present methodology for testing cigarettes for tar and nicotine ought to be changed at this time. However, the issues raised by RJR and Philip Morris and supported by Lorillard are sufficiently important that the Commission ought to encourage resolution of the problem in a manner that will be acceptable after critical scientific review.

There are two questions that have not been adequately answered by the submissions to the Commission. To what extent is the smoke of Barclay cigarettes diluted? How reliable are conclusions that could be drawn from the Gori cotinine study?

The dilution data provided chiefly by Philip Morris and supported by Reynolds are highly suggestive. On the other hand, the studies suffer from two flaws. The use of a device, particularly one as bulky as the PPA, may introduce a distortion in the manner in which cigarettes are smoked. This objection is met, in part, by internal controls, but remains a problem. More importantly, the panel used for the tests was potentially biased. Even if it were not so, the structure of a panel imposes misgivings. To quote from page 10 of the August 19 submission by RJR, they..."found isolated panel tests to be variable and unreliable unless very careful tests are performed under highly controlled conditions". With reservations expressed by one of the supporters, it is difficult to accept panel data collected under conditions where bias is possible and perhaps unavoidable.

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The Gori cotinine study purports to show that regardless of how the cigarette is smoked, the same amount of smoke is retained by the consumer of Barclay cigarettes as by smokers of Cambridge, Carlton or Now cigarettes. If so, the values obtained using the FTC smoking machine parameters are a fair measure of the relative risk to smokers of those four cigarettes. The Gori study is flawed, insofar as reported, in two major respects. There is no indication of brand of cigarettes smoked by the subjects prior to enrollment in the study. This is important because smokers of 1 mg. cigarettes may be habituated to substantially different deliveries of nicotine. For example, a Barclay smoker might be expected to compensate on being switched to a brand such as Cambridge or Carlton delivering only two-thirds as much nicotine. If so, such a smoker would increase the efficiency of tar recovery from the low-nicotine cigarettes, reducing any differences that might otherwise appear. That such compensation could occur is explicitly accepted in the design of the study itself. The baseline cotinine values suggest that a problem of this sort might be involved in the study. The second flaw in the Gori study is that there was an insufficient range of cigarette delivery to permit evaluation of dose-depedence of the cotinine levels. Such information is not necessary for the main thrust of the Gori argument. But if it were available, it would be useful in determining whether the Gori tests could detect differences in cigarette delivery, where such differences are detected in FTC tests.

How might these two questions be fully resolved? It may be possible to design a dilution study that would be acceptable to both industry and non-industry scientists. Design of such a study should almost certainly require participation of experts who are familiar with panel-testing of cigarettes. It may be possible to measure changes in blood levels of cotinine in smokers of moderate tar delivery cigarettes (e.g. 4-8 mg. tar) who switch to either Barclay or one of the other brands delivering from .1 to .3 mg. of nicotine. This would tell us whether, in this test, Barclay differs from moderate yield and low yield cigarettes.

I look forward to receiving more information with respect to these matters as it is available. A final report will be submitted at that time.

Sincerely yours,

Fred G. Bock

Fred G. Bock, Ph.D.
Director
Orchard Park Laboratories

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